

May 28, 2015



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 16361

EXPIRATION DATE: December 31, 2015

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: The University of Cincinnati
Cincinnati, OH
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of certain Division 6.2 Category A infectious substances in an alternative packaging (a freezer). No more than one freezer may be transported under the terms of this special permit. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196 in that alternative packaging is authorized.
5. BASIS: This special permit is based on the application of The University of Cincinnati dated January 12, 2015 submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Infectious substances, affecting humans*	6.2	UN2814	N/A

*Only cultures and animal tissue samples containing *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Burkholderia mallei*, and *Burkholderia pseudomallei* may be transported under the terms of this special permit.

7. SAFETY CONTROL MEASURES:

a. PACKAGING -

(1) PACKAGING METHOD A -

(i) INNER PACKAGING - Leakproof cryovials (primary receptacles) with a capacity of not more than 1.5 mL must be capped and placed in a cardboard box with water resistant coating containing not more than thirty-six (36) primary receptacles. Multiple primary receptacles placed in the cardboard box must be either wrapped individually or separated to prevent contact between them.

(ii) INTERMEDIATE PACKAGING - Not more than five (5) inner packages are placed in a plastic bag that is then sealed. Sufficient absorbent material must be placed between the inner packages and the plastic bag to absorb the entire contents of all primary receptacles in case of cryovial breakage or leakage.

(2) PACKAGING METHOD B -

(i) INNER PACKAGING - Plates (primary receptacles) with not more than ninety-six (96) wells, each well with a capacity of not more than

200 µL, must be covered and placed in a small sealable plastic bag containing not more than 3 primary receptacles.

(ii) INTERMEDIATE PACKAGING - Not more than six (6) inner packages are placed in a plastic bag that is then sealed. Sufficient absorbent material must be placed between the inner packages and the plastic bag to absorb the entire contents of all primary receptacles in case of plate breakage or leakage. Bags containing inner packages must be additionally placed within plastic containers of various sizes as specified in the application on file with the Office of Hazardous Materials Safety Approvals and Permits Division.

(3) OUTER PACKAGING - A freezer, constructed of steel and high impact plastic with insulation containing not more than eighty-eight (88) inner packages as described in paragraph 7.a.(1)(i) above and containing not more than one hundred and fifty-eight (158) inner packages as described in paragraph 7.a.(2)(i) above. Voids in the storage space of the freezer must be filled with sufficient amounts of absorbent material to prevent the contents from shifting.

b. OPERATIONAL CONTROLS -

(1) This special permit authorizes the transportation of one package (one freezer) containing infectious substances using a specialized transport vehicle under exclusive use from the University of Cincinnati Medical Sciences Building to Wright-Patterson Air Force Base, Building 840A, WPAFB, Ohio.

(2) The transport vehicle must be brought as closely as possible to the freezer during loading of the freezer into the transport vehicle.

(3) No more than one freezer may be transported under the terms of this special permit. Once the freezer is delivered to Wright-Patterson Air Force Base, Building 840A, WPAFB, Ohio, transportation of the freezer under the terms of this special permit is prohibited.

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(4) The temperature of the freezer must be monitored during the transit. The infectious substances in the freezer must be kept frozen at all times at the operating temperature range between -80 °C and -30 °C. The transport vehicle must be equipped with an environmental control system as a backup capable of turning on power to maintain a temperature at -30 °C or below in case of accidental loss of temperature control in the freezer.

(5) The freezer must be secured against movement in the transport vehicle. The freezer must be equipped an advanced electronic access control system with a locking mechanism activated and deactivated by a Personal Identification Number. The freezer doors must be securely closed and locked at all times during transportation.

(6) Spill response procedures must be in place and operational to address loss of desired temperature, delay in transportation, or release of an infectious substance.

(7) An itemized list of contents must be enclosed between the intermediate packagings and the outer packaging.

8. SPECIAL PROVISIONS:

a. Under the terms of this special permit, the grantee may only offer hazardous materials (i.e., the grantee is not authorized as a carrier).

b. Transportation is authorized under exclusive use carriage from The University of Cincinnati to the Wright-Patterson Air Force Base in Ohio.

c. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package and it is reoffered for transportation in conformance with this special permit and the HMR.

d. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.
11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
 - o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
 - o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
 - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 Immediate notice of certain hazardous materials incidents, and 171.16 Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

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